

**REMARKS**

In response to the pending Notice of Non-Compliant Amendment, the Applicants have changed the claim identifiers for withdrawn claims 2, 16, 34, 41, 44, 47, 49 and 50 to read “withdrawn-currently amended.” No other changes have been made from the Amendment filed November 21, 2007.

For the Examiner’s convenience, the text of the Remarks from the November 21, 2007 response is repeated, below. However, prior to reaching these remarks, the Applicants must note the following for the purpose of preserving the record for subsequent patent term adjustment.

The Notice Was Erroneously Issued, And The Patent Term Should Be Extended Accordingly. The original Notice of Non-Compliant Amendment mailed December 5, 2007 was issued on the ground that the amended withdrawn claims were incorrectly identified as “withdrawn,” and should have been identified as “withdrawn – currently amended.” The Notice of Non-Compliant Amendment was erroneously issued, as the MPEP expressly states that withdrawn claims which are being currently amended may be identified solely by the word “withdrawn”:

Any non-elected claim which are being amended must have either the status identifier (withdrawn) or (withdrawn – currently amended) and the text of the non-elected claims must be presented with markings to indicate the changes.”

MPEP § 714.C(A) (emphasis added). Because the issuance of the Notice of Non-Compliant Amendment has resulted in nearly two years of Office-generated delay in the prosecution of the present Application, the Applicants reserve the right to claim a corresponding patent term extension upon close of prosecution.

The Previously Submitted Remarks.

Claims 1, 2, 5, 7-10, 13, 15, 17-19, 22-25, 27, 30, 33, 35, 40 and 46 were examined in the pending Office Action, with claims 2, 4, 6, 11-12, 14, 16, 20-21, 26, 28-29, 31-32, 34, 36-30, 41-45, and 47-51 standing withdrawn pursuant to Election/Restriction Requirement.

The Applicant has amended independent claim 1 to further recite features of the present invention, and to incorporate the limitations of dependent claim 5. The Applicant has also amended withdrawn independent claim 2 into dependent form, depending from claim 1. In view of this amendment, the Applicant respectfully requests withdrawal of the Election/Restriction Requirement and consideration of claim 1 and all of the claims depending from claim 1: claims 2-4, 7, 10, 15-16, 18, 23-25, 29-32, 34, 40-41, 43-44, 46-47 and 49-51.

The following objections and rejections are currently pending:

- Objection to claims 22 and 27 as being of improper dependent for failing to further limit their previous claims.
- Rejection under 35 U.S.C. § 112, second paragraph, of claims 5, 15, 24, 33, 40 and 46 for antecedent basis issues.
- Rejection of claims 1, 3, 7-9, 13, 17-19, 22-25, 27, 30 and 35 under 35 U.S.C. § 103(a) as unpatentable over Admitted Prior Art in view of U.S. Patent Publication No. 2002/0054826 ("Frost").
- Rejection of claim 15 under § 103(a) as unpatentable over Admitted Prior Art and Frost, in further view of U.S. Patent No. 5,283,033 to Dodrill ("Dodrill").
- Rejection of claim 33 under § 103(a) as unpatentable over Admitted Prior Art and Frost, in further view of U.S. Patent No. 6,685,895 to Lin ("Lin").
- Rejection of claims 40 and 46 under § 103(a) as unpatentable over Admitted Prior Art and Frost, in further view of U.S. Patent No. 4,771,630 to Croce, *et al.* ("Croce").

1. **The Objection to Claims 22 and 27 Is Moot.** The Applicant has canceled claims 22 and 27, without prejudice to the subject matter therein, rendering the pending claim objection moot.

2. **The § 112 Rejections Have Been Addressed.** The Applicants have amended the claims to eliminate the identified antecedent basis issues. Withdrawal of the § 112 rejections is respectfully requested.

3. **The Amended Claims Are Patentable Over Frost, *Et Al.*** The Applicant respectfully traverses the rejections under § 103(a) based on the Frost reference, on the ground that this reference fails to teach or suggest all of the features of the present invention recited in claim 1 and its dependent claims, and Frost's deficiencies are not cured by the remaining cited references.

**The Invention Recited In Claim 1.** Claim 1 recites a process in which a gas permeable packaging is sterilized on its outside without significant amounts of hydrogen peroxide steam being introduced in the interior of the packaging. This is the result of the use of a vapor mix of water steam and hydrogen peroxide steam which does not penetrate into the interior of the packaging because the vapor mix is introduced to the sterilization area abruptly so that it immediately condenses upon contact with the gas permeable packaging, and then is immediately removed by rapid evacuation. This is unlike known sterilization processes with sterilization gases which cannot be effectively excluded from the packaging interior.

As amended, claim 1 now recites a process for operating a packaging transport system, comprising the steps of:

sterilizing objects packed in at least one layer of packaging which is bacteria-impermeable and gas-permeable;

placing the sterilized objects packed in at least one layer of the at least one layer of packaging into an evacuable sterilization chamber in the form of a transfer lock;

pre-evacuating the sterilization chamber, wherein the speed of the pre-evacuation is adapted to the flow resistance of the gas-permeable packaging to ensure a gas pressure within the packaging remains above a pressure in the sterilization chamber during the pre-evacuation;

applying abruptly a vapor mix consisting of water steam and hydrogen peroxide steam as a condensate layer onto the outer side of the packaging;

re-evacuating the sterilization chamber to remove the condensate layer and the uncondensed vapor mix before either the vapor mix or the condensate layer penetrates through the packaging to the objects at an inadmissible level; and

transferring the sterilized objects and packaging into a sterile clean room.

The Frost Reference. The Frost reference teaches the use of abrupt introduction of a vapor mix followed by evacuation of the sterilization chamber to sterilize “all accessible surfaces of the objects” in the chamber. Frost ¶ [0033]. Throughout Frost, this reference teaches that its object is to penetrate all available openings with the vapor compound to sterilize all surfaces of an object. *See, e.g.*, Frost ¶ [0022] (objects to be sterilized include bottles with internal surfaces).

In the pending Office Action, it is stated that with a contact time of less than 3 seconds, the vapor mix of Frost does not penetrate through the packaging at an inadmissible level. August 21, 2007 Office Action at 5. The cited paragraph in Frost does not support this summary conclusion (which the Applicant respectfully notes is presented without reference to any support,

contrary to the guidance provided in the recently issued *Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103(a) in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*).

Rather than providing a suggestion for a new approach to sterilization of the outer surfaces of *gas permeable* packages, Frost ¶ [0033] only states that all the surfaces of the object are contacted by the condensing vapor, and that this contact may be completed in as little as three seconds. Thus, regardless of what Frost teaches as to the amount of time the condensate is in contact with all the surfaces in the sterilization chamber, Frost does not contain any suggestion of the present invention's use of a "layer of packaging which is bacteria-impermeable and gas-permeable" in combination with control of process parameters such that "a gas pressure within the packaging remains above a pressure in the sterilization chamber during the pre-evacuation" and re-evacuation of the sterilization chamber is conducted "before either the vapor mix or the condensate layer penetrates through the packaging to the objects at an inadmissible level." Frost therefore does not teach or suggest the present invention's approach to sterilizing only the outside of a *gas permeable* package.

Moreover, rather than the Frost reference teaching the present invention, the Applicant notes that from the perspective of one of ordinary skill in the art, it was very surprising to find that the inventive process can be used in a process for operating a packaging transport system and for objects packed in a packaging which is gas permeable, as it was not foreseen that the condensate layer itself would provide an effective barrier to prevent the vapor compound penetrating

into the package. *See, e.g.*, Present Specification ¶ [0015] (discussing the unexpected sealing effect from the rapid coalescing of drops and closing off of gas permeable cover pores). Frost, which is entirely silent as to such an effect, therefore does not provide any teaching or suggestion of the present invention to one of ordinary skill in the art.

The remaining cited references do not provide the teaching or suggestion missing from the Frost reference.

The Zimmerman reference is cited as teaching adapting of the speed of the pre-evacuation to the flow resistance of the gas permeable cover of the transport container to ensure that a gas pressure within the covered transport container remains above a pressure in a chamber. The Applicant respectfully submits that Zimmerman does not provide any such teaching.

Zimmerman is directed to sealing packages with gas *impermeable* plastic sheets in which food products are vacuum-sealed. *See, e.g.*, Zimmerman at 3:16-43 (describing the vacuum sealing process). Of course, such vacuum-packaged products necessarily utilize packaging which must in the normal state always be impermeable to gas flow, lest the vacuum in the packaging be lost shortly after packaging. Thus, as a first matter, Zimmerman's vacuum-sealed packaging apparatus is non-analogous art vis-à-vis gas permeable packaging.

As to the portion of the Zimmerman disclosure cited in the pending Office Action (6:1-25), this disclosure discusses only verification of the sealing of the impermeable plastic packaging by subjecting the package to a temporary vacuum. There is no description of anything which can be fairly described as a

pre-evacuation step, let alone any adjustment of speed of the evacuation associated with an expected rate of gas flow through a porous gas permeable membrane (obviously, because the Zimmerman vacuum packaging plastic sheets are gas impermeable). Thus, Zimmerman does not teach or suggest the features of claim 5 (now incorporated in amended claim 1) for which it is cited, and one of ordinary skill in the art would not have considered combining the teachings of this reference with Frost.<sup>1</sup>

Because the Frost reference does not teach or suggest all of the features of the present invention for which it is cited, and these deficiencies are not cured by the remaining cited references, amended claim 1 and its dependent claims are patentable over these references under § 103(a). Reconsideration of the pending § 103(a) rejections, and rejoinder of the previously withdrawn claims in view of the amendment of claim 2 into dependent form, is respectfully requested.

### **CONCLUSION**

In view of the foregoing amendments and remarks, the Applicant submits that claims 1-4, 7, 10, 15-16, 18, 23-25, 29-32, 34, 40-41, 43-44, 46-47 and 49-51 are in condition for allowance. Early and favorable consideration and issuance of a Notice of Allowance for these claims is respectfully requested.

If there are any questions regarding this response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

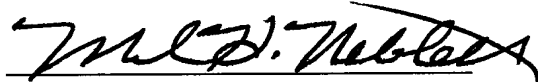
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<sup>1</sup> The Dodrill reference is also directed only to manipulation of packaging which is not gas permeable, and uses processes which would not be suitable for use with gas permeable packaging. *See, e.g.*, Dodrill at 14:29-33 (referring to a "vacuum sealed package").

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket # 029082.53185US).

Respectfully submitted,

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